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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,812	03/28/2001	Biaoyang Lin	P-IS 4373	5002

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/821,812	LIN, BIAOYANG	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *24 August 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *see attached*.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *38*.

Claim(s) objected to: *25*.

Claim(s) rejected: *24, 26, 34-37 for reasons already of record, because the amendment is not and will not be entered.* .

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment of 05/24/04 is not and will not be entered, because new claim 72 requires new 112, first paragraph rejection concerning the new issue of how to make such an amino acid sequence with any conservative substitutions at any position, such that they would be overexpressed in prostate cancer tissue as compared to normal prostate tissue, similarly to SEQ ID NO:5.

The following are answers to Applicant's arguments.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

Rejection under 35 USC 112, first paragraph of claims 24, 26, 34-37 pertaining to lack of a clear written description of variants of SEQ ID NO:5 remains for reasons already of record in paper of 02/24/04.

A. Regarding claims 24, 34, 37, Applicant asserts that the specification teaches a variety of ARP3 polypeptides such as species mammalian or non-mammalian homolog of human ARP3, that are defined by reference to the human ARP3 sequence of SEQ ID NO:5 and the recitation of at least 45% amino acid identity to the specified sequence.

Applicant argues that the claims 24, 34, 37 have been cancelled, and thus the rejection should be removed.

Applicant's arguments set forth in paper of 05/24/04 have been considered but are not deemed to be persuasive for the following reasons:

Rejection remains, because the amendment is not and will not be entered.

Further, it is noted that structure of species homologs such as a mammalian or non-mammalian homolog of human ARP3 is not disclosed in the specification. The specification fails to describe variants of SEQ ID NO:5 by the test set out in Lilly. The specification describes only a single polypeptide, SEQ ID NO:5. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus the claims encompass unrelated sequences with unknown structure and function, provided that said sequences have at least 45%, 65%, 75%, 85% or 95% identity with SEQ ID NO:5.

B. Regarding claim 26, Applicant argues that as set forth in the specification, an ARP3 fragment includes an exact stretch of at least 10 amino acids of the full length ARP3 sequence (SEQ ID NO:5), shown in figure 3. Applicant argues that thus the specification clearly describes ARP3 polypeptide fragments, which contain a portion of the human ARP3 amino acid sequence of SEQ ID NO:5.

Applicant's arguments set forth in paper of 05/24/04 have been considered but are not deemed to be persuasive for the following reasons:

The claim encompasses sequences of unknown structure and function, such as fragments of variants of the ARP3 polypeptide of SEQ ID NO:5 of any length, and unknown structure, that are attached to or contain a fragment of at least 10 contiguous amino acids of SEQ ID NO:5.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Rejection under 35 USC 112, first paragraph of claims 24, 26, 34-37 pertaining to lack of enablement for variants of SEQ ID NO:5 remains for reasons already of record in paper of 02/24/04.

A. Regarding claims 24, 34-37, Applicant argues that it is only routine work to make and use the claimed variants of SEQ ID NO:5 (ARP3 polypeptides), for example as antigens for preparation of monoclonal antibodies or antisera. Applicant argues that using the guidance in the specification one would be able to prepare an ARP3 polypeptide having one or more amino acid substitution, deletions or insertions as compared to SEQ ID NO:5.

Applicant argues that the claims 24, 34, 37 have been cancelled, and thus the rejection should be removed.

Applicant's arguments set forth in paper of 05/24/04 have been considered but are not deemed to be persuasive for the following reasons:

Rejection remains, because the amendment is not and will not be entered.

The claims encompass unrelated sequences with unknown structure and function, provided that said sequences have at least 45%, 65%, 75%, 85% or 95% identity with SEQ ID NO:5. Applicant has not taught how to make these variants of SEQ ID NO:5, having one or more amino acid substitution, deletions or insertions as compared to SEQ ID NO:5, such that they would still have the function of SEQ ID NO:5. One cannot predict the claimed variants would have the characteristics and function of SEQ ID NO:5, in view of the unpredictability of protein chemistry, and in view that that

even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein as taught by Burgess et al, Lazar et al, Tao et al, and Gillies et al, all of record .

B. Regarding claim 26, Applicant argues that the claimed polypeptide fragment contains exactly the sequence of a portion of the full-length Ar3 sequence (SEQ ID NO: 5), the portion having at least ten contiguous amino acids. Applicant argues that thus, claim 26 does not encompass “variants" of SEQ ID NO:5 but rather is directed to sub-parts of the full-length native human sequence. Applicant argues that all that would. have been required for one skîlled in the art to make and use the invention would have been to chemically synthesize a stretch of at least ten contiguous nmino acids of SEQ ID NO:5, using the sequence of SEQ ID NO:5 provided in Figure 3, and to use such a fragment as an immunogen using routine techniques as set forth in the specification.

Applicant’s arguments set forth in paper of 05/24/04 have been considered but are not deemed to be persuasive for the following reasons:

It is noted that the language “an ARP3 polypeptide” of claim 26, which is not immediately accompanied by a sequence identification number, encompasses an ARP3 variant polypeptide, especially in view of the disclosure in the specification of a variety of ARP3 polypeptides, including species ARP3 homologs of the human ARP3 of SEQ ID NO:5.

The claim encompasses sequences of unknown structure and function, such as fragments of variants of the ARP3 polypeptide of SEQ ID NO:5 of any length, and

unknown structure, that are attached to or contain a fragment of at least 10 contiguous amino acids of SEQ ID NO:5.

Since the structure and function of the claimed fragment is not known, one would not know how to make and use the claimed fragment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

September 15, 2004